CLAIM AMENDMENTS

The following Listing of Claims will replace all prior versions and listing of claims in the application.

Listing of Claims

1. (previously presented) A self-emulsifying drug delivery system comprising a mixture of an extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant, wherein the polyvinylpyrrolidone has a molecular weight of about 2,500 to about 20,000.

2. (previously presented) The self-emulsifying drug delivery system of claim 1, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3, and the weight ratio of said surfactant to said polyvinylpyrrolidone is about 10:1 to about 1:1.

3. (original) The self-emulsifying drug delivery system of claim 1, wherein the extremely water-insoluble, lipophilic active agent has a log P equal or greater than 2, and the extremely water-insoluble, lipophilic active agent has a solubility of less than 100 micrograms per milliliter of water.

Claims 4-5 (canceled).

6. (original) The self-emulsifying drug delivery system of claim 1, wherein the amount of polyvinylpyrrolidone is about 5% to about 40%, by weight of the self-emulsifying drug delivery system.

7. (original) The self-emulsifying drug delivery system of claim 1, wherein the amount of fatty acid is about 5% to about 35%, by weight of the self-emulsifying drug delivery system.

8. (original) The self-emulsifying drug delivery system of claim 1, wherein the amount of fatty acid is about 5% to about 15%, by weight of the self-emulsifying drug delivery system.

9. (original) The self-emulsifying drug delivery system of claim 1, wherein the fatty acid is a fatty acid containing from about 6 to about 18 carbons.

10. (original) The self-emulsifying drug delivery system of claim 9, wherein the fatty acid is selected from the group consisting of hexanoic acid, octanoic acid, nonanoic acid, decanoic acid, lauric acid, linoleic acid, oleic acid, palmitic acid, and mixtures thereof.

11. (original) The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxylated castor oil, polyoxylated glycerides of fatty acids, polyoxyethylene sorbitan fatty acid esters, polyglycolyzed glycerides, and mixtures thereof.

12. (original) The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxyl 35 castor oil and polysorbate 80.

13. (original) The self-emulsifying drug delivery system of claim 1, wherein the amount of surfactant is about 20% to about 70%, by weight of the self-emulsifying system.

14. (original) The self-emulsifying drug delivery system of claim 13, wherein the amount of the surfactant is about 30% to 50%, by weight of the self-emulsifying system.

15. (original) The self-emulsifying drug delivery system of claim 1, further comprising an antioxidant selected from the group consisting of ascorbic acid, ascorbyl palmitate, butylhydroxyanisole, butylhydroxytoluene, propyl gallate, sodium ascorbate, tocopherol, and mixtures thereof.

16. (original) The self-emulsifying drug delivery system of claim 1, further comprising a pharmaceutically acceptable organic solvent.

17. (original) The self-emulsifying drug delivery system of claim 14, wherein the solvent is selected from the group consisting of ethanol, a polyethylene glycol, propylene glycol, and mixtures thereof.

18. (original) The formulation of claim 1, comprising:

about 1 wt. % to about 4 wt. % said active agent;

about 5 wt. % to about 40 wt. % said polyvinylpyrrolidone;

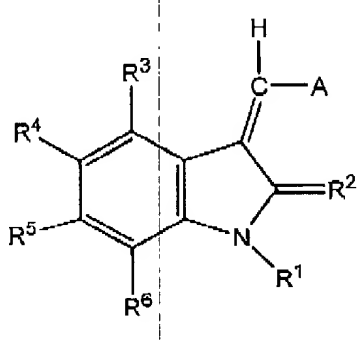
about 5 wt. % to about 35 wt. % said fatty acid; and

about 20 wt. % to about 70 wt. % said surfactant.

19. (original) The formulation of claim 1, wherein the active agent is a steroid, an anticancer agent, an antifungal agent, or antiinfective agent.

20. (original) The formulation of claim 1, wherein the active agent is selected from the group consisting of progesterone, ketoconzaole, itraconazole, metroxyprogesterone, and paclitaxel.

21. (withdrawn) The formulation of claim 1, wherein the active agent is a compound of the formula:



or a pharmaceutically acceptable salt, analog, or prodrug thereof, wherein:

R^1 is H or alkyl;

R^2 is O or S;

R^3, R^4, R^5, and R^6 are each independently selected from the group consisting of hydrogen, alkyl, alkoxy, aryl, aryloxy, alkaryl, alkaryloxy, halogen, trihalomethyl, S (O) R, SO_2NRR', SO_3R, SR, NO_2, NRR', OH, CN, C(O)R, OC(O)R, NHC(O)R, $(CH_2)_nCO_2R$, and CONRR';

A is a five membered heteroaryl ring selected from the group consisting of thiophene, pyrrole, pyrazole, imidazole, 1,2,3-triazole, 1,2,4-triazole, oxazole, isoxazole, thiazole, isothiazole, 2-sulfonylfuran, 4-alkylfuran, 1,2,3-oxadiazole, 1,2,4-oxadiazole, 1,2,5-oxadiazole, 1,3,4-oxadiazole, 1,2,3,4-oxatriazole, 1,2,3,5-thiadiazole, 1,3,4-thiadiazole, 1,2,3,4-thiatriazole, 1,2,3,5-thiatriazole, and tetrazole, wherein said ring is optionally substituted at one or more positions with alkyl, alkoxy, aryl, aryloxy, alkaryl, alkaryloxy, halogen, trihalomethyl, S(O)R, SO_2NRR', SO_3R, SR, NO_2, NRR', OH, CN, C (O) R, OC (O) R, NHC (O) R, $(CH_2)_nCO_2R$ or CONRR';

N is 0-3; and

R and R' are each independently H, alkyl or aryl.

22. (withdrawn) The formulation of claim 21, wherein the active agent is a compound of formula (I) wherein A is pyrrole optionally substituted with a substituent selected from the group consisting of alkyl, alkoxy, halogen, and -COR.

23. (withdrawn) The formulation of claim 21, wherein the active agent is 3-[(2,4-dimethylpyrrol-5-yl)methylene]-2-indoline or a salt, analog, or prodrug thereof.

24. (withdrawn) The formulation of claim 21, wherein the active agent is 3-[2,4-dimethyl-5-(2-oxo-1,2-dihydroindol-3-ylidenemethyl)-1*H*-pyrrol-3-yl]propionic acid or a salt, analog, or prodrug thereof.

25. (original) The formulation of claim 1, wherein the formulation is filled into a gelatin capsule.

26. (original) The formulation of claim 25, wherein the gelatin capsule is a hard-shelled gelatin capsule, a soft-shelled gelatin capsule, or a hydroxypropyl methylcellulose capsule.

27. (original) The formulation of claim 1, wherein the formulation is administered orally, parenterally, rectally, or topically.

28. (withdrawn) A method of treating and/or preventing a condition in need of a therapeutic regimen comprising a steroid, an antifungal agent, an antibacterial agent, or an anticancer agent, the method comprising the step of administering a self-emulsifying system comprising a mixture of a therapeutically effective amount of at least one extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant to an individual in need thereof, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3.

29. (withdrawn) The method of claim 28, wherein the weight ratio of said surfactant to said polyvinylpyrrolidone is about 10:1 to about 1:1.

30. (withdrawn) The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent has a log P of equal or greater than 2, and the extremely water-insoluble, lipophilic anticancer active agent has a solubility of less than 100 micrograms per milliliter of water.

31. (withdrawn) The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is an anticancer agent selected from the group consisting of paclitaxel or an indolinone compound.

32. (withdrawn) The method of claim 28, wherein the formulation is administered in combination with at least one additional active agent.

33. (withdrawn) The method of claim 32, wherein the formulation is administered in combination with an active agent selected from the group consisting of vascular endothelial growth factor, 5-fluorouracil, leucovorin, irinotecan HCl, epirubicin, taxotere, taxol, carboplatin, gemcitabine, cisplatin, oxaliplatin, 5-azacitidine, a signal transduction inhibitors, a cytostatic compound, and mixtures thereof.

34. (withdrawn) The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is a steroid, an antifungal agent, or antibacterial agent selected from the group consisting of progesterone, ketoconazole, itrazole, and metroxyprogesterone.

35. (withdrawn) Use of a composition comprising an extremely water-insoluble, lipophilic active agent, polyvinylpyrrolidone, a fatty acid, and a surfactant, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3, for the manufacture of a medicament for a condition in need of a therapeutic regimen comprising an active agent selected from the group consisting of a steroid, an antifungal agent, an antibacterial agent, and an anticancer agent.